



## Undisclosed conflicts of interest

### Case study 1

Source: Committee on Publication Ethics, [Case 04/13](#)

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### Undeclared competing interests

A journal published an animal study on the use of drug X for the treatment of clinical condition A. The authors did not declare any competing interests. A few months after publication, a journalist contacted the editors to say that the corresponding author had several patents on drug X, was listed as an inventor of the drug, and that the public charity of which he is the director recently announced that they were seeking approval for clinical trials of drug X in condition B. He also said the corresponding author co-owned a commercial company with whom the charity does business.

The authors were asked to clarify any competing interests, and were directed to the journal's policy, which is posted online as part of the instructions for authors.

The corresponding author replied saying that the commercial company was a subsidiary of the charity and had no ownership rights to the drug. He did not specifically say whether there were any competing interests to declare. Instead, he wanted to know how this matter had come to light.

During a telephone conversation he confirmed that the charity had applied for a patent for the use of the drug for the treatment of clinical condition A, but it was yet to be approved. He also said that no company had been licensed to develop/manufacture the drug for either condition. However, he also said that if the drug was ever licensed, the charity might choose to pass on some of the royalties to the inventors.

It was suggested that the following competing interest statement should be published: "Authors 1, 2 and 3 are employees of the not for profit institute, which has applied for a patent for the use of drug X in the treatment of clinical condition A. The institute is a public charity that currently holds patents for the use of drug X in other clinical conditions, with Author 1 listed as an inventor."

- Should the authors have included a competing interest declaration on the manuscript?
- If so, should it be any different to what was suggested?
- In general, what should be done about studies on drugs that are potentially lucrative? Should the authors declare if they "might" make money?
- In this case, what does "not-for-profit" really mean?
- And what does all this mean for researchers at universities that make

money through spin-off companies?

### ***Discussion***

- In the interests of transparency the authors should have declared a conflict of interest.
- The holder of a patent should declare that they hold such a patent even if any profits made go elsewhere, because they stand to derive an intangible benefit from being associated with that patent.
- There is nothing wrong with having a conflict of interest, but it must be declared. This allows readers to decide for themselves the relevance of the conflict of interest to the paper's conclusions.
- It is good practice for journals to ensure that they have a clear policy on conflict of interest.
- Some journals send the paper back to the original reviewers and ask them to comment on whether the conflict of interest would have changed their opinion on the paper.
- Retraction of a paper for an undeclared conflict of interest would only be considered in very serious cases where this seemed to undermine the validity of the data.
- The publication of a correction about the undeclared conflict of interest is usually the most appropriate course of action.
- The reference to the not-for-profit institution was a red herring as there was a potential for the authors to still receive both financial and non-financial benefits from the product.

### ***Action***

- The editor should publish a correction stating the nature of the undeclared conflict of interest.
- The journal should also consider whether they need to state their conflict of interest policy more clearly.

### ***Outcome***

A new correction was drafted, which excluded the authors' affiliation to a non-profit organisation. The editors contacted the corresponding author to let him know of the change, why it had been done, and to ask for his approval of the reworded correction. The new correction read as follows:

"In our recent article,[1] we failed to declare the following competing interests:

A, B, and C are employees of X Institute, which has applied for a patent for the use of drug N in the treatment of Condition A. The Institute currently holds patents for the use of N in other clinical conditions, with D listed as an inventor."

The corresponding author said that he would not agree with a declaration that did not mention that his institution is a public charity. He also stated that he felt the guidelines for declaring competing interests posted in the instructions for authors were not explicit enough.

The editors responded that the "non-profit" status of the institution was not

relevant, potential competing interests might still exist, and that it should be declared.

The author refused to consent to a declaration that did not mention "non-profit" and wanted to contact COPE to discuss the matter in more detail. The author also threatened legal action if the editors proceeded to publish the correction without his consent. He suggested a new draft for the text of the correction.

In our recent article [1], we did not declare the patent rights related to N technology. Since they may potentially be viewed as non-financial competing interests, despite the fact our employer is a non-profit public charity, we are now providing the following supplemental information: A, B and C are employees of X Institute, which has applied for a patent for the use of N in the treatment of Condition A. X Institute currently holds patents for the use of N in other clinical conditions, with D listed as an inventor."

To clarify the journal's position, the editors decided to post the following comment on the correction, which the author also agreed to:

"[The publisher] thanks the authors for clarifying their competing interests and wishes to make clear its view that even employees of non profit public charities may have competing interests (financial or otherwise) and that it is always best to err on the side of declaring these. However, at the time of publication of the original article, our competing interests policy was not sufficiently explicit on this point. We will, therefore, be updating it in due course."

Resolution: Unknown to COPE.